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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,193	07/10/2006	Gerd Dahms	4266-0110PUS1	7394

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
03/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/550,193	DAHMS ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09212005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-15 are cancelled and claims 16-31 are newly added in a preliminary amendment filed on 09/21/2005.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 20 of copending Application No. 2007/0105746 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application No. 2007/0105746 A1 claims a composition and method of preparing a composition for "targeted release of fragrances and/or aromas in the form of solid lipid nanoparticles (SLN) dispersion in which lipid-based nanoparticles are present which are stabilized by

an emulsifier monoloayer, one or more membrane layers or other auxiliaries, the fragrances and/or aromas being included in the nanoparticles and/or in the emulsifier monolayer or the membrane layers, preparable by a) mixing the fragrance and/or aroma with the lipid-based active ingredient carrier and at least one emulsifier, which leads, in stage b), to the formation of a lyotropic liquid-crystalline mixed phase, at temperature above the melting or softening point of the active ingredient carrier, to form a phase B, where lipids and emulsifiers are used in a weight ratio of from 50:1 to 2:1, b) mechanical mixing of the phase B with an aqueous phase or polyol phase A which can comprise and emulsifier, at a temperature above the melting or softening point of the active ingredient carrier, where the weight of phase B to phase A is 1:5 to 5:1, without high-pressure homogenization, to form a lyotropic liquid-crystalline mixed phase, c) dilution of the mixed phase with an aqueous phase or polyol phase which can comprise an emulsifier, at a temperature of the aqueous phase or polyol phase which is below the melting or softening point of the active ingredient carrier, with stirring and without high-pressure homogenization, to a desired end concentration of the dispersion." (See claims 14 and 20).

However, Application No. 2007/0105746 A1 does not claim any particular particle average diameter. The instantly claims particle diameter range, 10 to 10, 000nm, would have been obvious to one of ordinary skill in the art at the time of the instant invention. One would have been motivated to arrive at the instant particle diameter range through routine optimization in order to provide a composition that is clear. (See paragraph

0044). For the foregoing reasons, instant claims 16 and 22 are obvious over claims 14 and 20 of Application No. 2007/0105746 A1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-20, 22 and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Domb (US Patent 5188837, Published 02/23/1993).

Domb teaches, "microsuspension contain lipospheres, which are solid, water-insoluble microparticles that have a layer of phospholipid embedded on their surface. The core of the liposphere is a solid substance to be delivered, or a substance to be delivered that is dispered in an inert solid vehicle, such as wax." (See abstract). In a preferred embodiment Domb teaches a method of preparing lidocaine liposheres with polycaprolactone. The liposphere is prepared by mixing 100mg of lidocaine, 500mg of polycapralactone, and 200mg lecithin in a 20ml vial. The vial is heated to 65°C to melt the polycapralactone and dissolve the lidocaine. 10ml hot aqueous buffer solution was added to the vial and the formulation was mixed well by vigorous hand shaking and by vortex for about 5 minutes. The formulation was immediately cooled to room temperature by immersing the vial in a dry ice-acetone bath with continued shaking. The

lipospher**e** had a particle size of less than 10, 000 nm. (See column 5, Lines 58-68, column 6, Lines 1-40 and column 8, Lines 44-55). The formulation was lyophilized to dryness and reconstituted with 3ml of sterile water and vortexing for 1 minute. (See column 9, Lines1-12). For the foregoing reasons, the instant claims are anticipated by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 16, 17, 20-22, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speiser (US Patent 4880634, Published 11/14/1989).

Applicant Claims

Applicant claims a method of producing an aqueous vehicle dispersion having an average particle diameter in the range from 10 to 10,000 nm, prepared by mixing an active compound with wax, polymer or lipod- based carrier and an emulsifier at a

temperature above the melting or softening of the carrier to form a phase B. Phase B and an aqueous A at weight ratio between 1:5 to 5:1 is mechanically mixed at a temperature above the melting or softening point of the carrier. Finally, the mixed phase is diluted with an aqueous phase and stirred at a temperature below the melting or softening point of the carrier.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Speiser teaches, "Lipid nano-pellets as excipient system for perorally administered drugs". (See title). In a preferred embodiment an 800nm nanopellet is formed by mixing 2.0g of Tween 80, 0.2g of beclobrat, and stearyl alcohol at 70°C. The mixture is then added to 178g heated water and the dispersed by ultrasonic treatment at 35 kHz. The suspension is then cooled and diluted with 100g of water, giving a suspension concentration of 7.4%. (See column 11, Lines 5-21). "[T]he lipid nano-pellet are present in the suspension in a concentration from 1-20% by weight." (See abstract).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Speiser teaches a dispersion where in step b the ratio of phase B to phase A is 1:8. However, Speiser makes the ratio of phase B to phase A instantly claimed, 1:5 to 5:1, obvious.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to adjust the amount of water to be added to the lipid phase taught

by Spieser to arrive at the instantly claimed ratio. One would have been motivate to do so in order to adjust the concentration of the nano-pellets in the dispersion and therefore the amount of active agent administered. For the foregoing reasons the instant claims would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2. Claims 23-25, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speiser (US Patent 4880634, Published 11/14/1989) in view of De Vringer (US Patent 5667800, Published 09/16/1997)

Applicant Claims

Applicant claims a method of producing a multiple dispersion by mixing an aqueous dispersion of nanparticles with polyol phase or oil phase.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Speiser is discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Speiser et al. lacks a teaching wherein the aqueous dispersion is further mixed with a polyol phase or oil phase. This deficiency is cured by the teachings of De Vringer.

De Vringer teaches, "The suspension of solid lipoid nanoparticles in an aqueous liquid thus produced, can be used as such on the skin ... Alternatively, this suspensio, with or without the presence of a topically effective medicament, can further be mixed with an appropriate, preferably aqueous, polar liquid, with liquid or semisolid lipid, or a

mixture thereof which may in its turn be a w/o emulsion such as an ointment or an o/w emulsion such as lotion, cream or a gel." (See column 5, Lines 12-25). "Liquid or semisolid lipids which may be mixed, as such or in w/o or o/w emulsion, with the suspenision of solid liquid nanoparticles according to the invention are for example: waxes, such as jojoba oil; minerl oils, such as liquid or soft paraffins; ..." (See column 5, Lines 48-64).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Speiser with De Vringer. One would have been motivate to do so in order to provide the dispersion of Speiser in an ointment or lotion for topical application. For the foregoing reasons the instant claims would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
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/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616